

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-34. (Cancelled)

35. (Currently Amended) A method of delivering a ~~lipophilic bioactive material~~ paclitaxel to an ~~interior all~~ inner wall of a ~~body blood~~ vessel of a patient from an implantable medical device having an expandable balloon with the ~~lipophilic bioactive material~~ paclitaxel on an outer surface of the balloon, the method comprising the steps of:

~~inserting the balloon into a body vessel, the~~  
providing an angioplasty balloon having a dried layer  
containing the ~~paclitaxel bioactive material~~ on the outer surface of the balloon, the balloon being free of a coating atop the ~~dried layer bioactive material~~, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer; and further wherein the balloon has folds, and portions of the dried layer containing paclitaxel are positioned in the folds;

advancing the balloon within the ~~body~~blood vessel to  
a treatment site within the ~~body~~blood vessel;

inflating the balloon at the treatment site to contact  
~~the bioactive material~~the balloon with an inner wall of the  
~~body~~blood vessel;

maintaining the ~~bioactive material on the outer~~  
~~surface of the inflated balloon in contact with the inner~~  
~~wall of the body~~blood vessel ~~while the balloon is inflated~~  
so as to transfer paclitaxel to the inner wall of the blood  
vessel;

deflating the balloon after said  
maintaining; ~~contacting the bioactive material with the~~  
~~inner wall of the body vessel~~; and

removing the deflated balloon from the ~~body~~blood  
vessel.

36. (Previously Presented) The method of Claim 35,  
wherein the balloon is inflated at the treatment site with  
an inflation time of up to about one minute.

37. (Cancelled)

38. (Currently Amended) The method of Claim ~~37~~35, wherein the ~~bioactive material~~ dried layer further comprises a diagnostic agent.

39. (Cancelled)

40. (Currently Amended) The method of Claim ~~39~~35, wherein the ~~body~~blood vessel is a coronary artery.

41. (Currently Amended) The method of Claim 35, wherein at said providing step, the implantable medical device includes a total of about 5 to about 500  $\mu$ g of the ~~lipophilic bioactive material~~ paclitaxel on the outer surface of the balloon. ~~prior to inserting the medical device into the body vessel.~~

42. (Currently Amended) The method of Claim 35, wherein the method is performed without implanting a stent within the ~~body~~blood vessel.

43. (Previously Presented) The method of Claim 35, wherein the balloon comprises a material selected from the

group consisting of: a polyamide, polypropylene, PEBAX and polyethylene.

44. (Currently Amended) The method of Claim 35, wherein the dried layer consists essentially of the implantable ~~medical device is a balloon catheter coated with a single layer of the lipophilic bioactive material on the balloon, the single layer consisting essentially of about 5 to about 500  $\mu$ g of paclitaxel or a paclitaxel derivative deposited~~ on the outer surface of the expandable balloon.

45. (Cancelled)

46. (Currently Amended) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with about 0.2 to about 20  $\mu$ g of paclitaxel or a paclitaxel derivative deposited per  $\text{mm}^2$  of the outer surface of the expandable balloon and a total of about 5 to about 500  $\mu$ g of the paclitaxel or the paclitaxel derivative deposited on the outer surface of the expandable balloon; and wherein the method further includes at least one of:

percutaneous insertion of the expandable balloon into  
the patient; ~~a blood vessel~~;

inflation of the balloon at the treatment site with an  
inflation time of up to about one minute to contact the  
paclitaxel or the paclitaxel derivative with the inner wall  
of the ~~body~~blood vessel; or

maintaining the outer surface of the inflated balloon  
in contact with the inner wall of the ~~body~~blood vessel for  
only the period of the inflation of the balloon.

47. (Currently Amended) The method of Claim 35, wherein  
the implantable medical device is a balloon catheter having  
an expandable balloon with a total of about 5 to about 500  
 $\mu$ g of paclitaxel or a paclitaxel derivative deposited on  
the outer surface of the expandable balloon;

the expandable balloon is percutaneously inserted into  
a the patient ~~blood vessel~~;

the balloon is inflated at the treatment site with an  
inflation time of up to about one minute to contact the  
paclitaxel or paclitaxel derivative with the inner wall of  
the ~~body~~blood vessel; and

the outer surface of the inflated balloon is maintained in contact with the inner wall of the ~~body~~blood vessel for only the period of the inflation of the balloon.

48. (Currently Amended) The method of Claim 35, wherein at said providing step, the implantable medical device is a balloon catheter having an expandable balloon with a total of about 0.2 to about 20  $\mu\text{g}$  of paclitaxel or a paclitaxel derivative per  $\text{mm}^2$  of the outer surface of the expandable balloon ~~before inserting the balloon into the body vessel~~.

49. (Currently Amended) A method of delivering a ~~lipophilic anti-angiogenic agent~~ paclitaxel to an ~~interior~~ inner wall of a blood vessel from a balloon catheter having an expandable balloon with a coating on an outer surface of the balloon, the method comprising:

~~inserting a portion of the~~ providing a balloon catheter including ~~the~~ a balloon with a dried coating consisting of paclitaxel or a mixture of paclitaxel with another bioactive agent ~~the lipophilic anti-angiogenic agent~~ ~~into a body vessel~~, the dried coating being free of any additional coating atop the dried coating, ~~anti-angiogenic agent~~, where the ~~anti-angiogenic agent~~ paclitaxel or

mixture of paclitaxel with another bioactive agent is not incorporated within a containment layer, and where the balloon has folds and portions of the dried coating are positioned in the folds;

advancing the balloon within the ~~body~~ blood vessel to a treatment site;

inflating the balloon to directly contact the ~~anti-angiogenic agent in the coating~~ paclitaxel or mixture of paclitaxel with another bioactive agent with an inner wall of the ~~body~~ blood vessel; and

delivering the ~~anti-angiogenic agent~~ paclitaxel or mixture of paclitaxel with another bioactive agent to the inner wall of the ~~body~~ blood vessel while maintaining the ~~anti-angiogenic agent~~ paclitaxel or mixture of paclitaxel with another bioactive agent in direct contact with the inner wall of the ~~body~~ blood vessel while the balloon is inflated.

50. (Cancelled)

51. (Previously Presented) The method of Claim 49, where the balloon is attached to a catheter shaft that includes a

guide wire lumen and an inflation lumen for inflating the balloon.

52. (Currently Amended) The method of Claim 49, where the ~~anti-angiogenic agent~~ paclitaxel or mixture of paclitaxel with another bioactive agent is brought into direct contact with the vessel wall only while the outer surface of the inflated balloon is maintained in contact with the inner wall of the ~~body~~ blood vessel.

53. (Currently Amended) The method of Claim 52, where the method is performed without implanting a stent within the ~~body~~ blood vessel.

54. (Currently Amended) A method of delivering paclitaxel to an interior wall of a blood vessel from a balloon catheter having an expandable balloon with a paclitaxel coating on an outer surface of the balloon, the method comprising:

~~inserting the~~ providing a balloon catheter without a stent ~~into a body vessel~~, the balloon catheter having a dried coating consisting of about 5 to about 500 micrograms of a single bioactive coating material consisting of



paclitaxel per 25 mm<sup>2</sup> of the gross outer surface area of the balloon, ~~the coating being free of any additional coating~~ and balloon catheter being free of any coating atop the paclitaxel, where the paclitaxel is not incorporated within a containment layer and amounts of the paclitaxel are deliverable to the interior wall upon direct contact of the paclitaxel with the interior wall, and where the balloon has folds and amounts of the dried coating are positioned in the folds;

advancing the balloon within the bodyblood vessel to a treatment site within the bodyblood vessel;

inflating the balloon at the treatment site to directly contact the paclitaxel in the coating with an ~~inner wall~~ the interior wall of the bodyblood vessel and thereby deliver paclitaxel to the interior wall without implanting a stent within the bodyblood vessel. ~~and~~  
~~—delivering the paclitaxel to the inner wall of the body vessel while maintaining the paclitaxel on the outer surface of the inflated balloon in direct contact with the inner wall of the body vessel while the balloon is inflated.~~